

REMARKS

This Amendment is made in response to the Office Action mailed May 29, 1990, and following a meeting with the Examiner on July 13, 1990. Claims 11, 54, 57-60, 63, 66, 69, 72, 75, 81, 84, 90 and 91 have been canceled, and claims 7, 52-56, 64, 67 and 85 have been amended. Entry of the above amendments is respectfully requested.

The applicant would like to thank the Examiner for the courtesy extended to him at the personal interview held on July 13, 1990. At the interview, a fully functioning artificial heart representing one embodiment of the invention was demonstrated. A detailed discussion of the merits of the invention and the important characteristics that distinguish it from the prior art was held. The Examiner further clarified his reasons for rejecting claims 7 and 52-54, and indicated that with certain changes these claims and their dependent claims may be allowable. The Examiner also indicated that claim 16 is allowable without changes and that he would consider modifications and further remarks concerning the other claims.

Turning then to the action on the merits, claims 52, 70, 73 and 76 were rejected under 35 U.S.C. §102(a) as being anticipated by Moise. Applicant respectfully traverses this rejection.

A required element of the rejected claims is the minimally-hemolytic wear resistant blood-immersed journal bearing

means. Nowhere in Moise is a blood-immersed journal bearing means taught. Accordingly, applicant respectfully submits that the rejection under 35 U.S.C. §102 is improper and requests that it be withdrawn.

Claims 55-57, 64 and 67 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the expression "said annular blood channel" on line 4 of claims 64 and 67 is said to lack antecedent basis, and the expression "such as" in claims 55-57 is said to be indefinite.

Claims 64 and 67 have been amended to read "an annular blood channel"; claims 55-56 have been amended to delete the expression "such as"; and claim 57 has been canceled. Accordingly, it is respectfully submitted that the claims are definite, and it is requested that this rejection be withdrawn.

Claims 11, 58-60, 90 and 91 were rejected under 35 U.S.C. §112, first paragraph, for the reason that the specification allegedly fails to provide an enabling disclosure with respect to the control means to vary the cardiac output. Although applicant disagrees, these claims have been canceled. Accordingly, this rejection should be withdrawn.

Claims 54, 66, 69, 72, 75 and 84 were rejected under 35 U.S.C. §102(a) as being anticipated by Olsen et al. Again, while applicant disagrees, these claims have been canceled.

Claims 7, 8, 10, 16 and 61 were rejected under 35 U.S.C. §103 as being unpatentable over Moise. Applicant respectfully traverses this rejection.

Applicant has amended claim 7 in accordance with the discussion with the Examiner. The amendments have been made to clarify the meaning of the blood-pumping elements, and to better distinguish the present invention from Moise. The blood pumping elements are now specifically defined and the claim has been made more concise.

Moise principally teaches the structure and method of use of purge seals in blood pumps. It does not suggest their configuration for implantation within the heart.

Moreover, amended claim 7 of the present invention requires that the pumping means be non-thrombogenic. In Moise, this would require a source of purge fluid. Even if the membrane recirculator (100 in Moise Fig. 6) were used, Moise shows this as a separate component from the blood pump (10 in Moise Fig. 6) connected to it by tubes. Thus, although the size of the blood pump itself might be made small enough to fit within the heart, it would not constitute "non-thrombogenic pumping means to impart mechanical energy to the bloodstream" without a purge fluid supply. Moise does not suggest combining the blood pump and membrane recirculator in any configuration let alone a special configuration for implantation within the heart. There is no indication that the membrane recirculator could be made small enough for this to be

possible. Moise makes no mention or even suggestion of the implantation of his invention within the natural heart.

With respect to claim 10, the instant disclosure clearly indicates that the use of a porous outer layer to provide tissue ingrowth is for the purpose of preventing infection, by bringing antibodies and white blood cells to the immediate vicinity of the surface of the device, via capillaries from the myocardium. This is not obvious in view of the usual functions of tissue ingrowth for providing mechanical stability, a mechanical seal, or for providing endothelial cells on blood contacting surfaces to prevent thrombus.

Moreover, claims 8 and 10 are dependent upon claim 7 and therefore should be allowable for the same reasons that claim 7 is allowable. Similarly, claims 16 and 61 require a configuration for implantation within the heart, and claim 61, which is dependent upon claim 52, requires washing by high enough blood flow to prevent thrombus accumulation severe enough to cause failure of the pump. As already discussed, these are nowhere taught or suggested by Moise.

Accordingly, the present invention as claimed is neither taught nor suggested by Moise, and it is requested that this rejection be withdrawn.

Claims 52-54 and 58-84 were rejected under 35 U.S.C. §103 as being unpatentable over Wampler '712 in view of Olsen

et al. Applicant respectfully traverses this rejection as well.

The present invention as defined in the rejected claims is clearly distinguished from Wampler because Wampler requires a flush seal and the present invention does not require any seal. To more clearly distinguish the present invention from Olsen et al. which uses completely magnetically suspended rotors with "magnetic bearings", applicant has amended claim 52 and added the word "mechanical" to now require blood-immersed mechanical bearings. Also, claim 52 has been amended to indicate that all of the "exposed junctions" are washed by high enough blood flow to prevent thrombus accumulation severe enough to cause failure of the pump. In figure 29 there are two exposed junctions, one at 564 and another at 568. In figure 37a there is only one exposed junction, at 435. Referring to figure 38, junction 515 represents an exposed junction of the rotating and stationary components of the bearings, but also is a junction between the rotor and the stationary hub which supports the bearings. The present invention not only washes the bearings with high blood flow, but also washes the blood contacting surfaces of the entire flow path, including any exposed junctions between rotating and stationary components of the pump in addition to the bearings.

Claims 53 and 85 have been amended similarly to clearly distinguish the claimed invention from Olsen et al., and the other pending but rejected claims are dependent upon claims 52 and 53.

Therefore, it is respectfully submitted that these claims are also allowable for the same reasons that claims 52 and 53 are allowable.

Accordingly, applicant respectfully requests that this rejection be withdrawn.

Applicant appreciates the indication of allowability of claims 55-57 if rewritten to overcome the rejection under 35 U.S.C. §112 and to include all of the limitations of the base and intervening claims. Applicant also appreciates the indication of allowability of claims 85-89.

Applicant notes that the Official Action was made final. It is respectfully submitted that the finality of the Action is premature. For example, claims 55-57 and 76-78 were previously indicated to be allowable if rewritten in independent form. Claims 55-57 were not amended, but a new ground of rejection, under 35 U.S.C. §112, was made against them. Since applicant did nothing to these claims, nothing applicant did necessitated the new ground of rejection. Accordingly, the finality of the Office Action is premature, and applicant requests that it be withdrawn.

Applicant notes that the Information Disclosure Statement filed on March 14, 1990, was not considered because the particular relevancy of each reference to the instant invention has not been given. There is no such requirement under 37 C.F.R. §1.98. The relevance of each reference is given, as required. Applicant is not required to specifically distinguish the invention from each

reference in the Statement. Moreover, the references were already reviewed in application Serial No. 090,995.

In view of the above and all of the arguments of record, entry of the amendment, withdrawal of the finality of the Official Action, consideration of the Information Disclosure Statement, and favorable reconsideration and allowance of this application with all the pending claims 1-10, 12-53, 55, 56, 61, 62, 64, 65, 67, 68, 70, 71, 73, 74, 76, 77, 79, 80, 82, 83 and 85-89, are respectfully requested.

Respectfully submitted,

CURTIS, MORRIS & SAFFORD, P.C.  
Attorneys for Applicant

By John M. Kilcoyne  
John M. Kilcoyne  
Registration No. 33,100  
530 Fifth Avenue  
New York, New York 10036  
Telephone: (212) 840-3333